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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/994,998	11/27/2001	Sukant Tripathy	2328.2003-001	9119

7590

10/15/2003

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EXAMINER

TRUONG, DUC

ART UNIT

PAPER NUMBER

1711

DATE MAILED: 10/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/994,998	TRIPATHY ET AL.	
	Examiner	Art Unit	
	Duc Truong	1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>1009</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's arguments filed 9/4/03 have been fully considered but they are not persuasive. The Amendment submitted by Applicant does not overcome the rejection made by Examiner in the last Office action.

Note that claims 5-44 have been cancelled and new claim 45 has been added.

Claim 1 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chem Abstract 128: 162418.

Note that claim 1 has been amended to include the characteristics, "the compound is water soluble" and "if the one of more non-proteinaceous amphipathic groups are polyalkylene glycol groups, the polyalkylene glycol groups have a MW of about 5,000 to about 15,000".

The following position is taken because the claim is read as broadly as possible. Limitations from the specification or Remarks as to how the compound is produced are not read into the claim. The claim as presented are included in the broad teachings of the reference since they read on a compound comprising hematin derivatized with polyalkylene glycols produced from any methods having the claimed characteristics.

Applicant has presented no factual evidence to show why the products of the reference would not in fact have the claimed properties. Since the reference discloses the required composition in the claimed composition, then the claimed characteristics such as water-soluble, of MW such be considered inherent in the prior art.

Note also that claim 45 has been added to provide amphipathic groups.

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Since this is a new claim then a new ground of rejection is cited using the same reference.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chem Abstract 128: 162418 (U.S. 5,711,867)

The reference discloses a compound comprising hematin derivatized with one or more non-proteinaceous amphipathic groups such as polyalkylene glycol, as stated above.

The disclosure of the reference differs from the instant claim in that it does not disclose the broad teachings of amphipathic groups, as in the claim.

However, the reference does disclose the use of a diaminohexane having the same functionality with polyallylamine or polydiallylamine since they are included in polyamines then one can replace another. The reference further discloses the spacer arm (diaminohexane and polyethylene glycol are included) and broadly, the spacer arm used will depend upon the working electrode and coordination compound selected. That means more than two components can be used as spacer arm.

It would have been obvious to one of ordinary skill in the art to select diaminohexane or another one from the reference to replace other amphipathic groups since they have been shown to be effective in a similar system and thus would have

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been expected to provide adequate results. There is no showing of unexpected results derived from said selection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Duc Truong whose telephone number is 703-308-2437. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 703-308-2462. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

DT

A handwritten signature in black ink, appearing to read 'Duc Truong', with a stylized flourish at the end.

DUCTRUONG
PRIMARY EXAMINER

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chem Abstract 128: 162418.

The reference discloses a compound comprising hematin derivatized with one or more non-proteinaceous amphipathic groups such as polyalkylene glycol (see Abstract).

The disclosure of the reference differs from the instant claims in that it does not disclose the claimed characteristics such as soluble in solutions ranging from pH 1 to pH 12 and the claimed MW.

However, the composition disclosed by the reference is prepared from reactants and under process conditions that are inclusive of the claimed reactants and conditions. In view of this similarity, it would appear to be inherent that the product, a compound, having the claimed soluble in solutions ranging from pH 1 to pH 12 and the claimed

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MW, could be prepared following the teachings of the reference. See In re Best, 195 USPQ 430, 433 (CCPA 1977).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Duc Truong whose telephone number is 703-308-2437. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 703-308-2462. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

DT
May 29, 2003



DUCTRUONG
PRIMARY EXAMINER